Kawasaki Disease and RotaTeq® Vaccine

June 15, 2007

Important Information Regarding Kawasaki Disease and RotaTeq Vaccine

The Food and Drug Administration (FDA) approved today a revised label for RotaTeq, a rotavirus vaccine manufactured by Merck and Co., Inc. (**http://www.fda.gov/cber/products/rotateq.htm**), to include information on reports of Kawasaki disease occurring before and after the vaccine's licensure in February 2006. FDA has not made any changes to its indications for use of RotaTeq nor has it issued new or revised warnings or precautions. Likewise, the Centers for Disease Control and Prevention (CDC) has not made any changes in its recommendations regarding the use of RotaTeq. Healthcare providers and parents should remain confident in using RotaTeq in infants.

The FDA reports that five cases of Kawasaki disease have been identified in children less than 1 year of age who received the RotaTeq vaccine during clinical trials conducted before the vaccine was licensed. Three reports of Kawasaki disease were detected following the vaccine's approval in February 2006 through routine monitoring using the Vaccine Adverse Event Reporting System (VAERS). After learning about these Kawasaki disease reports, CDC identified one additional unconfirmed case through its Vaccine Safety Datalink (VSD) Project. The vaccine label has been revised to notify healthcare providers and the public about the reports of Kawasaki disease following RotaTeq vaccination.

The number of Kawasaki disease reports does not exceed the number of cases we expect to see based on the usual occurrence of Kawasaki disease in children. There is not a known cause-and-effect relationship between receiving RotaTeq or any other vaccine and the occurrence of Kawasaki disease.

The available data support the safety of the RotaTeq vaccine and its effectiveness in preventing rotavirus infection, a common cause of severe infant diarrhea and hospitalization. CDC and FDA continue to monitor the safety of RotaTeq and all vaccines.

KEY FACTS

- CDC is not changing its immunization policy at this time. The available data support the safety and effectiveness of the RotaTeq vaccine in preventing rotavirus infection. CDC continues to support the recommendations of the Advisory Committee on Immunization Practices (ACIP) for routine immunization of all U.S. infants with three doses of RotaTeq administered orally at ages 2, 4 and 6 months. (**www.cdc.gov/vaccines/pubs/ACIP-list.htm**)

- It is important to remember that the known benefits of the RotaTeq vaccine in preventing rotavirus disease – the cause of one of our most common and potentially severe childhood illnesses – outweigh any known risks to date. Rotavirus causes severe diarrhea, vomiting, fever and dehydration (gastroenteritis) in infants and young children. It is the leading cause of gastroenteritis in infants and children worldwide. Each year in the United States, rotavirus is responsible for more than 400,000 doctor visits; more than 200,000 emergency department visits; 55,000 to 70,000 hospitalizations; and between 20 and 60 deaths among children less than 5 years of age. Worldwide, rotavirus causes approximately 1,600 deaths each day among children less than 5 years of age.

- Approximately 6 million doses of RotaTeq have been distributed in the United States through June 8, 2007. The three Kawasaki disease reports submitted to VAERS since the vaccine's licensure on February 3, 2006, does not exceed the number of cases we expect to see based on the usual occurrence of Kawasaki disease in children.

- As of June 13, 2007, CDC's Vaccine Safety Datalink (VSD) Project reported one unconfirmed case of Kawasaki disease within 30 days of RotaTeq vaccination among 65,000 doses administered to children less than 1 year of age who are enrolled in the VSD Project. This case has not been reported to VAERS. The VSD finding does not represent an increased risk over what would be expected to occur naturally among children less than 1 year of age who did not receive RotaTeq. The VSD Project is a collaboration between CDC and eight managed care organizations (MCOs) for the purpose of monitoring and evaluating the safety of vaccines administered to enrolled patients. VSD will continue to monitor for Kawasaki syndrome following RotaTeq vaccination.

- The RotaTeq label has been updated to specifically include six cases of Kawasaki disease that were observed during the clinical trials conducted before the vaccine was licensed. There were five cases among the 36,150 recipients of RotaTeq and one case among the 35,536 placebo recipients. It is not known if RotaTeq played a role in these cases. Additionally, the label has been revised to include information that VAERS has received reports of Kawasaki disease. Since licensure on February 3, 2006, three reports of Kawasaki disease have been submitted to VAERS. In the VAERS reports, the children had received other childhood vaccines in addition to RotaTeq.

- Kawasaki disease is a serious illness in children of unknown cause and characterized by a high fever that lasts several days. Kawasaki disease causes inflammation of the walls of the small and medium sized arteries (vasculitis) throughout the body, including the coronary arteries. Kawasaki disease primarily occurs in young children, most under 5 years of age. It affects approximately 4,000 children in the United States each year. There is no disease-specific test to diagnose Kawasaki disease. A doctor diagnoses Kawasaki disease based on the presence of typical signs and symptoms. These include a high fever that lasts for five or more days, irritability, red eyes, bright red and cracked lips, a "strawberry" tongue, swollen hands and feet, peeling skin on the fingertips and toes, a rash and swollen lymph nodes. Prompt recognition of symptoms and appropriate treatment are essential in the care of Kawasaki disease.

- Kawasaki disease has been seen after a variety of infectious or environmental exposures including a prior respiratory illness, exposure to carpet-cleaning chemicals, use of a humidifier and living near a body of water. Kawasaki disease has not been linked to

vaccinations. There is no firm evidence that Kawasaki disease is caused by any of these factors.

- CDC and FDA continue to monitor the safety of RotaTeq and all vaccines and encourage healthcare providers and other individuals to report any cases of Kawasaki disease or other severe adverse events following vaccination to VAERS. For a copy of the vaccine reporting form, call 1-800-822-7967 or report online to **www.vaers.hhs.gov**.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
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Source: **http://www.cdc.gov/od/science/iso/concerns/kawasaki_disease_rotavirus.htm**

Massachusetts Department of Public Health (MDPH)
Division of Epidemiology and Immunization

MDPH requests that health-care providers note this label change for RotaTeq® and be alert for possible cases of Kawasaki disease in infants following administration of rotavirus vaccine.

- Please immediately report any possible cases of Kawasaki disease (or any other serious adverse event) following vaccination to the Vaccine Adverse Event Reporting System (VAERS) by calling 1-800-822-7967 or reporting on line to **www.vaers.hhs.gov**.
- MDPH would also like to know about any cases of Kawasaki disease following rotavirus vaccination in Massachusetts. After reporting to VAERS, please contact MDPH Immunization Program at 617-983-6800 to report any suspected or confirmed case.